REMARKS

Claims 1-44 were pending. With the present Response, Applicants amend Claim 1, 18, 31-33, and 34, cancel Claims 19-30, and add new Claim 45; therefore, Claims 1-18 and 31-45 remain pending for consideration. Applicants cancel Claims 19-30 for the sole purpose of simplifying the issues in the present application and to expedited prosecution. Applicants intend to submit and prosecute Claims 19-30 in a continuation in the near future.

Claim Rejections Under 35 U.S.C. § 112

Claims 1, 19, and 31-34

Claims 1, 19, and 31-34 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Office Action asserts that the language "along the sheath's entire axial length," "along the tubular ePTFE layer's axial length," "along the layer's axial dimension," and "at the proximal end" of Claims 1, 31, 32, and 34, respectively, and the language "from the proximal end to the distal end" of Claims 19 and 33 includes subject matter not described in the application as filed.

The M.P.E.P. explains, "To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." M.P.E.P. § 2163. With regard to a newly added claim limitation, the M.P.E.P. explains, "[N]ewly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure." Applicants respectfully traverse the rejection because the specification does indeed describe the claimed invention such that one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention, and because the newly added claim language is supported by express, implicit, or inherent disclosure.

For example, at least paragraphs [0067] through [0074] describe a polymeric sleeve 44 that would be understood by one of skill in the art to support the newly added language to the claims, as discussed above. In particular, paragraph [0073] explains that the physical characteristics of a sleeve can be optimized, "to achieve a polymeric sleeve 44 that can function . . . to isolate the aneurysmic sac while at the same time preventing tissue ingrowth through the wall in the landing zones of the sleeve 44." Paragraph [0073] further explains, "The landing

zones include the locations generally in the proximal and distal end regions of the sleeve 44 where it is in contact with native healthy intima of the vessel in which it is inserted." In the full context of the disclosure, one of skill in the art would necessarily understand the description above (i.e., the portion of the sleeve that isolates the aneurysmic sac with the landing zones) as describing "along the sheath's entire axial length," "along the tubular ePTFE layer's axial length," "along the layer's axial dimension," as well as, "from the proximal end to the distal end", as claimed.

Furthermore, the specification identifies "at the proximal end," with respect to the portion of paragraph [0073] quoted above describing the sleeve's landing zones (i.e., "The landing zones include the locations generally in the proximal and distal end regions of the sleeve 44 where it is in contact with native healthy intima of the vessel in which it is inserted.").

However, to simplify and expedite prosecution in this application, Applicants have amended the claims in a manner that renders the rejection moot. For example, "along the sheath's entire axial length" of Claim 1 has been deleted; "along the tubular ePTFE layer's axial length" of Claim 31 has been amended to "along portions of the tubular ePTFE layer's axial length which are in contact with a vessel wall" (and support for this language, can be found at least at paragraph [0073], as discussed above); and "along the layer's axial dimension" of Claim 32 has been amended to "through portions of the layer that contact a vessel wall when the prosthesis is implanted to span an aneurysm" (which is also supported at least by paragraph [0073], as discussed above).

In addition, Claim 19 has been canceled (rendering the rejection moot); "from the proximal end to the distal end" of Claim 33 has been deleted; and "at the proximal end" of Claim 34 has been deleted, as well. The new language of Claims 33 and 34 find support at least in paragraph [0073], as discussed above, as well.

For at least the foregoing reasons, Claims 1 and 31-34 satisfy the requirements of 35 U.S.C. § 112, first paragraph. Applicants therefore respectfully request withdrawal of the claim rejection.

Claim 18

Claims 18 stands rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. In particular, the Office Action indicates that the language, "the membrane having a membrane proximal end region and a membrane distal end region and configured to *inhibit* cellular growth through the membrane *which would be sufficient to enable* the formation of a thin, viable neointimal layer . . . ." is unclear as to how inhibiting cellular growth on the membrane enables the formation of a neointimal layer on the membrane (emphasis in Office Action).

The claim language is not intended to convey the concept that inhibiting cellular growth on the membrane enables the formation of a neointimal layer on the membrane, as proposed by the Office Action. Instead, the language explains that the membrane is configured to inhibit cellular growth through the wall of the membrane that itself would be sufficient to enable the formation of a thin, viable neointimal layer on the lumenal surface of the membrane. Therefore, Applicants respectfully traverse the rejection, as the claim as previously presented satisfies the requirements of 35 U.S.C. § 112, second paragraph. However, for the sole purpose of clarifying the language (and not for purposes of patentability), Applicants have amended Claim 18, as indicated above.

Applicants respectfully request withdrawal of this claim rejection, as well.

Claim Rejections Under 35 U.S.C. § 102/103

Claims 1-44 stand rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious in view of, U.S. Patent No. 6,197,049 to Shaolian, et al. Applicants respectfully traverse the rejection, as Shaolian neither anticipates nor renders obvious the rejected claims.

Claims 1, 18, and 31-34 recite, in one form or another, a sheath configured to inhibit sufficient cellular ingrowth through the wall of the sheath to permit the formation of a viable neointimal layer on the lumenal surface of the sheath (Claim 1); a membrane configured to inhibit cellular growth through the membrane sufficient to enable the formation of a thin, viable neointimal layer on the lumenal surface of the membrane at least at the membrane proximal and distal end regions (Claim 18); an ePTFE layer that prevents the formation and nourishment of a

viable neointimal layer therethrough along portions of the tubular ePTFE layer's axial length which are in contact with a vessel wall (Claim 31); a layer which prevents tissue ingrowth through portions of the layer that contact a vessel wall when the prosthesis is implanted to span an aneurysm (Claim 32); inhibiting formation of a viable neointima on a second side of a layer throughout the contacting portion, nourished through the layer (Claim 33); and a tubular sheath configured to inhibit the formation of a viable neointimal layer on the lumenal surface of the sheath through the wall of the sheath (Claim 34).

However, Shaolian fails to teach or suggest all of the claim language. For example, Shaolian fails to teach or suggest the language of Claims 1, 18, and 31-34, as discussed above. For this reason alone Shaolian cannot anticipate the rejected claims, as M.P.E.P. § 2131 provides, "To anticipate a claim, the reference must teach every element of the claim. 'A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.'" (citing Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987)).

Indeed, the Office Action itself fails to indicate specifically how Shaolian anticipates the claims. Instead, the Office Action generally points to Columns 6-21 (which is all but two and one-quarter columns of Shaolian's entire Detailed Description) for support. Such general references are prohibited under the Patent Rules. See 37 C.F.R. § 1.104(c)(2) (emphasis added) ("In rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command. *When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable*. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified.") Applicants believe the Office Action fails to identify particular language of Shaolian that anticipates the claims because no such language exists. Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) rejection.

In the alternative, the Office Action indicates that the Claims would have been obvious to one of ordinary skill in the art at the time the invention was made. The Office Action indicates, "Shaolian discloses the porosity characteristics of the sheath (44) may be either homogeneous throughout the axial length of the prosthesis or may vary according to the axial position along the prosthesis," citing column 6, lines 49-52. In addition, the Office Action explains, "Shaolian

teaches examples in which the sheath (44) is nonporous or provided with pores of relatively low porosity in areas where anchoring is less of an issue, and thus does not require endothelial growth," citing column 6, lines 61-67. "Therefore," the Office Action concludes, "it would have been obvious . . . to configure the sheath to inhibit cellular growth along the lumenal surface of the sheath's entire axial length, from the proximal end to the distal end, or at least a sheath's proximal or distal end regions in applications that do not require anchoring along the sheath's entire axial length, and one desires to do so."

However, this reasoning fails for several reasons. In short, while the implant of the present claims seeks to prevent tissue ingrowth in the landing zones, Shaolian teaches the desirability of such ingrowth.

First, even if Shaolian teaches that porosity characteristics may be either homogeneous or vary and that certain sheath portions can be nonporous, nothing in Shaolian teaches or suggests a sheath configured to inhibit sufficient cellular ingrowth through the wall of the sheath to permit the formation of a viable neointimal layer on the lumenal surface of the sheath (as in Claim 1); a membrane configured to inhibit cellular growth through the membrane sufficient to enable the formation of a thin, viable neointimal layer on the lumenal surface of the membrane at least at the membrane proximal and distal end regions (as in Claim 18); an ePTFE layer that prevents the formation and nourishment of a viable neointimal layer therethrough along portions of the tubular ePTFE layer's axial length which are in contact with a vessel wall (as in Claim 31); a layer which prevents tissue ingrowth through portions of the layer that contact a vessel wall when the prosthesis is implanted to span an aneurysm (as in Claim 32); inhibiting formation of a viable neointima on a second side of a layer throughout the contacting portion, nourished through the layer (as in Claim 33); or a tubular sheath configured to inhibit the formation of a viable neointimal layer on the lumenal surface of the sheath through the wall of the sheath (as in Claim 34). Instead, Shaolian actually teaches away from such language, as discussed below.

Second, the Office action cites portions of Shaolian out of context. For example, at column 6 lines 49-52, Shaolian explains, "The porosity characteristics of the polymeric sleeve may be either homogeneous . . . or may vary . . . ," but in the subsequent sentences of the same paragraph Shaolian explains, "In a preferred embodiment of the invention, the material of sleeve 44 is sufficiently porous to permit ingrowth of endothelial cells, thereby providing more secure

anchorage of the prosthesis and potentially reducing flow resistance, sheer forces, and leakage of blood around the prosthesis." More importantly, at column 6, lines 54-51 (emphasis added), Shaolian explains, "At least a proximal portion 55 and a distal portion 59 of the prosthesis 42 will seat against the native vessel wall, proximally and distally of the aneurysm. ***In these proximal and distal portions, the prosthesis preferably encourages endothelial growth, or, at least, permits endothelial growth to infiltrate portions of the prosthesis in order to enhance anchoring and minimize leakage***." Therefore, Shaolian teaches away from methods and devices having the structures as claimed.

In addition, Shaolian only describes the central portion of a prosthesis (e.g., the portion that spans an aneurysm) as potentially being "nonporous, or provided with pores of relatively lower porosity." See column 6, lines 61-67. However, nowhere does Shaolian teach or suggest a method or structure having the characteristics as claimed. Indeed, as discussed above, he actually teaches away from such methods and structures.

Shaolian teaches away from the present claims throughout his specification. For example, at column 6, lines 41-45, Shaolian explains (emphasis added):

> In a preferred embodiment of the invention, the material of sleeve 44 is sufficiently porous to permit ingrowth of endothelial cells, thereby providing more secure anchorage of the prosthesis and potentially reducing flow resistance, sheer forces, and leakage of blood around the prosthesis.

Therefore, Shaolian's sleeve is designed to permit ingrowth of endothelial cells. The passage above provides explains certain advantages in doing so, as well. Shaolian provides further discussion of the advantages and desirability of permitting tissue ingrowth at lines 40-61 of the same column (emphasis added):

> The porosity characteristics of the polymeric sleeve 44 may be either homogeneous throughout the axial length of the prosthesis 42, or may vary according to the axial position along the prosthesis 42. For example, referring to FIGS. 1 and 2, different physical properties will be called upon at different axial positions along the prosthesis 42 in use. At least a proximal portion 55 and a distal portion 59 of the prosthesis 42 will seat against the native vessel wall, proximally and distally of the aneurysm. In these proximal and distal portions, the prosthesis preferably encourages endothelial growth, or, at least, permits endothelial growth to infiltrate portions of the prosthesis in order to enhance anchoring and minimize leakage.

Therefore, again, Shaolian's sleeve, encourages endothelial growth, at least its proximal and distal portions. Nowhere does Shaolian teach or suggest the language of Claims 1, 18, or 31-34, as discussed above.

Shaolian continues by explaining that anchoring the portion of the prosthesis that spans an aneurysm is less of an issue than anchoring the prosthesis at its ends. Shaolian provides at column 6, lines 61-67:

> A central portion 57 of the prosthesis spans the aneurysm, and anchoring is less of an issue. Instead, maximizing lumen diameter and minimizing blood flow through the prosthesis wall become primary objectives. Thus, in central zone 57 of the prosthesis 42, the polymeric sleeve 44 may either be nonporous, or provided with pores of relatively lower porosity.

Nothing in the above passage, or anywhere else in Shaolian, teaches or suggests the language of Claims 1, 18, and 31-34 as discussed above. Indeed, at column 7, lines 1-10, Shaolian continues to explain the importance of cell growth and its ability to secure proximal and distal attachment zones of a support having exposed wires at its ends, as follows (emphasis added):

> A multi-zoned prosthesis 42 may also be provided in accordance with the present invention by positioning a tubular sleeve 44 on a central portion 57 of the prosthesis, such that it spans the aneurysm to be treated, but leaving a proximal attachment zone 55 and a distal attachment zone 59 of the prosthesis 42 having exposed wires from the wire support 46. In this embodiment, the exposed wires 46 are positioned in contact with the vessel wall both proximally and distally of the aneurysm, such that the wire, over time, may become embedded in cell growth on the interior surface of the vessel wall.

Finally, at column 13, lines 38-44, Shaolian once again explains that when positioned within an artery, endothelialization of the graft's polymeric sleeve will occur (emphasis added):

> In general, the graft will be positioned within an artery having a slightly smaller interior cross-section than the expanded size of the graft. This enables the graft to maintain a slight positive pressure against the wall of the artery, to assist in retention of the graft during the period of time prior to endothelialization of the polymeric sleeve 44.

Therefore, Shaolian fails to teach or suggest, or render obvious, the language of Claims 1, 18, and 31-34. For example, Shaolian fails to teach or suggest, or render obvious, at least a sheath configured to inhibit sufficient cellular ingrowth through the wall of the sheath to permit the formation of a viable neointimal layer on the lumenal surface of the sheath as in Claim 1; a membrane configured to inhibit cellular growth through the membrane sufficient to enable the

formation of a thin, viable neointimal layer on the lumenal surface of the membrane at least at the membrane proximal and distal end regions as in Claim 18; an ePTFE layer that prevents the formation and nourishment of a viable neointimal layer therethrough along portions of the tubular ePTFE layer's axial length which are in contact with a vessel wall as in Claim 31; a layer which prevents tissue ingrowth through portions of the layer that contact a vessel wall when the prosthesis is implanted to span an aneurysm as in Claim 32; inhibiting formation of a viable neointima on a second side of a layer throughout the contacting portion, nourished through the layer as in Claim 33; and a tubular sheath configured to inhibit the formation of a viable neointimal layer on the lumenal surface of the sheath through the wall of the sheath as in Claim 34.

Finally, the Office Action fails to establish that one of skill would have been motivated to extend Shaolian's nonporous central portion to the sheath's ends, or along its entire length. Instead, the Office Action merely proposes that one of skill would have found it obvious to configure a sheath as claimed "in applications that do not require anchoring along the sheath's entire axial length, and [if] one desires to do so." However, Office Action fails to indicate any applications that do not require anchoring or any reason that one of skill would desire to do so. In contrast, Shaolian himself explains the importance of anchoring, and provides no reason to provide a method or device as claimed.

For at least these reasons as well, one of skill in the art would not have found the claimed inventions obvious in view of Shaolian. Therefore, Claims 1, 18, and 31-34 distinguish over the applied art. Claims 2-17 depend from Claim 1 and Claims 35-44 depend from Claim 34; therefore, Claims 2-17, 20-30, and 35-44 distinguish over the applied art as well. In addition, Claims 2-17, 20-30, and 35-44 distinguish over the applied art for the unique combination of features recited therein.

Claims 19-30 have been canceled, as discussed above. Cancellation of these claims renders the associated rejection moot.

New Claim 45

New Claim 45 finds support throughout the original specification, as filed. For example, Figures 17 and 33 illustrate a prosthesis having a single opening at its proximal end and two

openings at its distal end such that the prosthesis is configured for implantation at a vascular bifurcation.

Furthermore, Claim 45 depends from Claim 34, which distinguishes over the applied art for the reasons provided above. Therefore, Claim 45 distinguishes over the applied art for at least the same reasons. Claims 45 also distinguishes over the applied art for the unique combination of features recited in the claim.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

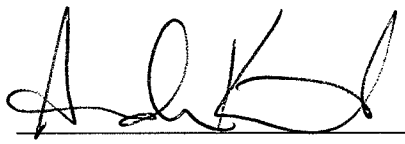
In view of the foregoing amendments and remarks, Applicants submit that this application is in condition for allowance and such action is respectfully requested. If any issues remain or require further clarification the Examiner is respectfully requested to call Applicants' counsel at the number indicated below in order to resolve such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 7, 2008

By: 

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